

REMARKS

The present reply is intended to be fully responsive to all points of objection and/or rejection raised by Examiner and is believed to place the application in a condition for allowance. No new matter has been introduced by any of the amendments, if any, to the specification. Applicant respectfully requests reconsideration and withdrawal of Examiner's objections and rejections in view of the foregoing amendments and following remarks.

Claims 7, 9-11 and 18-26 are currently pending in the present application. The claims stand as follows:

- Claims 1-6 previously withdrawn
- Claim 7 amended
- Claim 8 cancelled
- Claims 9-11 amended
- Claims 12-17 previously withdrawn
- Claim 18 amended
- Claims 19-21 no change this reply
- Claims 22-23 amended
- Claims 24-25 no change this reply
- Claim 26 amended
- Claims 27-31 previously withdrawn

CLAIM OBJECTIONS

Claim 9

Examiner objected to dependent claim 9 because the original language, "the valve," made it unclear as to which valve the claim limitation referred. Claims 7, 9-11, 23, and 26 are amended to clarify this language and to bring specificity to the claim elements. Withdrawal of this objection is respectfully requested.

CLAIM REJECTIONS – 35 U.S.C. § 103

Examiner rejected claims 7-11, 18, 19, 22, 23, 25, and 26 under 35 U.S.C. § 103(a) as being unpatentable over US 5,707,356 to Paul in view of US 6,315,752 to DiMatteo. More specifically, Examiner stated:

Claims 7, 10, and 26

Regarding Claims 7, 10, and 26, Examiner stated:

In the specification and figures, Paul discloses the apparatus as claimed by applicant. With regard to claims 7, 10, and 26, Paul discloses a pressure relief valve that is designed for use during heart surgery in an extracorporeal circuit (see column 2, lines 8-46). The valve 10 comprises a body 12 with a first inlet 14 with an axis parallel to the direction of flow (see arrow in FIG 1), a second inlet 47 with an axis parallel to flow through the inlet, and an outlet 16 with an axis parallel to flow (see FIGS 1-2, column 3, column 4, lines 16-33)). First inlet 14 comprises a one-way duckbill valve 18 that is capable of allowing fluid from a patient's body towards the outlet (see FIG 3). The second inlet 47 comprises a two-way valve 32 that comprises inlet umbrella 34 and outlet umbrella 36 that is capable of allowing fluid to pass from a source into the valve body towards the outlet in the event of a negative pressure situation and outward from the valve into the source 47 in the event of a positive pressure situation (see column 3).

Paul fails to disclose that the first and second inlet are disposed at an angle of less than 90 degrees, but does disclose that various flow axes are contemplated within the scope of the invention (see column 4, lines 40-41). However, DiMatteo discloses a bypass graft that passes blood through the lumens of tubes 200, 210. The inlet lumens at 211, 202 are disposed at an acute angle, that is less than 90 degrees, in order to reduce turbulence between the flows entering from both lumens (see FIG 2, column 4, lines 7-15). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to arrange the inlets of the Paul device to have less than 90 degrees between them as disclosed by DiMatteo in order to reduce turbulence in the flow through the main lumen, as taught by DiMatteo.

This rejection is respectfully traversed. Claims 7, 10, and 26 are each amended to clarify language used to distinguish the elements of the apparatus and not to overcome the prior art. Claim 7 now more clearly reflects that the second inlet comprises a coupling means to couple it with a source to prevent the entry of air in the line when the flow control device opens due to negative pressure.

All limitations of the claimed invention must be considered when determining patentability. *In re Lowry*, 32 F.3d 1579, 1582, 32 U.S.P.Q.2d 1031, 1034 (Fed. Cir. 1994). Neither Paul nor DiMatteo, either alone or in combination, teach or suggest each of the claim limitations of amended independent Claim 7.

Paul neither teaches nor suggests a second inlet with a coupling means for connecting the second inlet to a source to prevent the entry of air in the line when the flow control device opens due to negative pressure. Instead, Paul consistently teaches the use of an “ambient air conduit” that expressly allows the entry of air into the line when a negative pressure threshold is reached (col. 4, ll. 16-24). No means is provided in Paul to couple the “ambient air conduit” to any other device. To the contrary, the “ambient air conduit” is intended to remain uncoupled so as to be exposed to ambient air.

The “ambient air conduit” (47), as it is consistently referred to by Paul, is always exposed to the *ambient air*. If one were to connect a source of saline to it, the “ambient air conduit” would no longer function as an ambient air conduit but rather a saline conduit. This is counter to the teachings of Paul. Moreover, Paul consistently refers to this “ambient air conduit” as a required element of the device in independent claims 1, 5, and 6. Further, Paul discusses the importance that this “ambient air conduit” (47) be open to the ambient air so as to allow visual inspection of the valve condition (col. 2, ll. 33-36).

For these reasons, Applicant strongly believes that Claim 7 is nonobvious despite the teachings of Paul. If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Consequently, Applicant believes that dependent Claims 10 and 26 are nonobvious as well. Applicant respectfully requests that Examiner reconsider the amended claims and withdraw this rejection.

Claim 8

Regarding Claim 8, Examiner stated:

With regard to claim 8, applicant's claim language is directed to the functional use of the claimed apparatus. It has been held that device claims cover what a device is, not what a device does. See MPEP 2114. In the instant case, applicant fails to disclose any additional structural limitations that distinguish the instantly claimed invention from that suggested by the prior art. Paul discloses that the inlet 47 is an ambient air conduit. However, the conduit is capable of being connected to a source of fluid, such as saline, which could relieve pressure in the circuit without introducing air into the circuit, thereby meeting the limitations of the claims.

Applicant agrees with Examiner's assertion that case law establishes that an apparatus claim covers what a device is and not what a device does. However, Claim 8 was not worded such that it indicated what the device (i.e., the valve of Claim 7) does. Instead, the language of Claim 8 was worded such that it further limited the type of two-way element of the valve (of Claim 7) to one that "relieves negative pressure in the line without introducing air into the line." This use of functional language to further limit a claim is entirely appropriate. *See In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997).

Problems using functional language to further limit a claim only arise when the functional limitation is shown to be an inherent feature of the cited prior. *In re Swinehart*, 439 F.2d 210, 213 (C.C.P.A. 1971). However, Examiner has not established that the valve of Paul inherently possessed this claimed functionality. Examiner's statement that the inlet of Paul is *capable* of being connected to a source of fluid, such as saline, is conclusory at best and is evidence that hindsight reconstruction was used to declare this claim as obvious. To the contrary, everything in Paul teaches that the ambient air conduit (reference numeral 47) is exactly that – *an ambient air conduit*.

Regardless, Claim 8 has been cancelled and its functional language incorporated into amended independent Claim 7. Because it is cancelled, Examiner's rejection of Claim 8 is no longer valid.

Claim 9

Regarding Claim 9, Examiner stated:

With regard to claim 9, it is unclear what valve applicant is referring to. However, Paul discloses that the status of valves 34, 36, may be visually ascertained, providing a visual indicator of flow within the valve (see column 3, lines 45-48).

If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Claim 9 depends upon Claim 7. Applicant strongly believes that Claim 7, as previously argued, is nonobvious in spite of the cited prior art. Consequently, Applicant believes that dependent

Claim 9 is nonobvious as well. Applicant respectfully requests that Examiner withdraw this rejection and reconsider this claim as presented.

Claims 11 and 23

Regarding Claims 11 and 23, Examiner stated:

With regard to claims 11 and 23, applicant claims only that the opening pressures of the valves may be modified. Paul discloses that the valve umbrellas are operable to open at particular pressures (see column 4, lines 16-34). However, it is the position of the examiner that the opening pressure of the valves may be adjusted as a part of the manufacturing process, forming the umbrella structure of a more or less resilient material in order to adjust the opening pressures of the valves. Since the valve disclosed by Paul is capable of being adjusted, or changed, to modify the opening pressures, the disclosures of the cited prior art meet the limitations of the claims.

With respect to claims 11 and 23, if an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Claims 11 and 23 depend upon Claim 7. Applicant strongly believes that Claim 7, as previously argued, is nonobvious in spite of the cited prior art. Consequently, Applicant believes that dependent Claims 11 and 23 are nonobvious as well. Applicant respectfully requests that Examiner withdraw this rejection and reconsider this claim as presented.

Claim 18

Regarding Claim 18, Examiner stated:

With regard to claim 18, the valve comprises opening 47 illustrated without any covering, which corresponds to a "transparent window," as broadly interpreted by the examiner (see FIG 2).

Claim 18 is amended to clarify what Applicant intended by the use of the term "window" in the original claim language. Claim 18 now reflects that a transparent surface on the valve body was intended which is distinguishable from Examiner's overly broad interpretation of the term. Claim 18 as originally presented claimed a "transparent window wherein fluid flow within the valve [could] be observed." Applicant obviously intended a *closed* window, or else the fluid flow would not be contained within the valve (i.e., pressure would cause the fluid to flow out of

the valve cavity). Examiner has attempted to broadly define “window” as an opening in the valve structure, as is provided in Paul (the “ambient air conduit”). In doing so, Examiner failed to consider the entirety of the language of the claim. Consequently, Applicant strongly believes that this rejection is invalid.

Further, if an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).). Claim 18 depends upon Claim 7. Applicant strongly believes that Claim 7, as previously argued, is nonobvious in spite of the cited prior art. Consequently, Applicant believes that dependent Claim 18 is nonobvious as well. Applicant respectfully requests that Examiner withdraw this rejection and reconsider this claim as presented.

Claim 19

Regarding Claim 19, Examiner stated:

With regard to claim 19, the indicator comprises the umbrella section 35a of valve 35 (see FIG 2), which deforms in response to pressure through valve 32, thereby indicating the presence of flow within valve 32.

With respect to claim 19, if an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Claim 19 depends upon Claim 7. Applicant strongly believes that Claim 7, as previously argued, is nonobvious in spite of the cited prior art. Consequently, Applicant believes that dependent Claim 19 is nonobvious as well. Applicant respectfully requests that Examiner withdraw this rejection and reconsider this claim as presented.

Claims 22 and 25

Regarding Claims 22 and 25, Examiner stated:

With regard to claims 22 and 25, Paul discloses that the second inlet 47 is an ambient air conduit, which allows fluid, such as air, to expel into open air in the event of excess pressure within the line.

With respect to claims 22 and 25, if an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Claims 22 and 25 depend upon Claim 7. Applicant strongly believes that Claim 7, as previously argued, is nonobvious in spite of the cited prior art. Consequently, Applicant believes that dependent Claims 22 and 25 are nonobvious as well. Applicant respectfully requests that Examiner withdraw this rejection and reconsider this claim as presented.

Claims 20 and 21

Examiner rejected claims 20 and 21 under 35 U.S.C. § 103(a) as being unpatentable over US 5,707,356 to Paul in view of US 6,315,752 to DiMatteo, further in view of US 4,747,826 to Sassano. More specifically, Examiner stated:

In the specification and figures, Paul and DiMatteo disclose the device substantially as claimed by applicant (see rejection above) with the exception of an electronic flow detector connected to a visual display. Sassano discloses a fluid flow system for rapid venous infusion that comprises tubing, valves, and means for sensing fluid flow. The device comprises fluid flow controllers 38 (which may include valves) and monitors coupled to infusion pump 14 (see column 4, lines 14-26). The flow sensors are electronic in nature and have a corresponding visual display (see column 6, lines 23-30). The system, including its sensors and controllers, allow for rapid, automated infusion to a patient that can be monitored by an operator consulting the display (see column 2, lines 16-40). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to couple an electronic fluid sensor with visual display, as disclosed by Sassano, with the valve suggested by the prior art in order to provide for easy fluid flow monitoring by a single operator, as taught by Sassano.

With respect to claims 20 and 21, if an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Claims 20 and 21 depend upon Claim 7. Applicant strongly believes that Claim 7, as previously argued, is nonobvious in spite of the cited prior art. Consequently, Applicant believes that dependent Claims 20 and 21 are nonobvious as well. Applicant respectfully requests that Examiner withdraw this rejection and reconsider this claim as presented.

Claim 24

Examiner rejected claim 24 under 35 U.S.C. § 103(a) as being unpatentable over US 5,707,356 to Paul in view of US 6,315,752 to DiMatteo, further in view of US 7,033,336 to Hogendijk et al. More specifically, Examiner stated:

In the specification and figures, Paul and DiMatteo disclose the device substantially as claimed by applicant (see rejection above) with the exception of providing a venous reservoir as the source of fluid for the second inlet passage. With regard to claim 22, Hogendijk discloses a catheter assembly with a first inlet 258 and a second inlet 224, and an outlet passage 213 wherein the second inlet is coupled to a venous return line (see column 7, lines 45-67, column 8 lines 1-8, FIG 6C). The second inlet is regulated by a valve 256 that opens if the negative pressure in outlet line 213 is too great, allowing for pressure relief such that high levels of suction related aspiration will not harm the patient's vessel (see column 3, lines 45-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a venous reservoir or source as disclosed by Hogendijk to the valve apparatus suggested by the prior art in order to prevent suction-related harm to the patient's vessel, as taught by Hogendijk.

With respect to claim 24, if an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Claim 24 depends upon Claim 7. Applicant strongly believes that Claim 7, as previously argued, is nonobvious in spite of the cited prior art. Consequently, Applicant believes that dependent Claim 24 is nonobvious as well. Applicant respectfully requests that Examiner withdraw this rejection and reconsider this claim as presented.

CONCLUSION

Applicant has adopted the Examiner's suggestions, where applicable, and believes the claims are now in condition for allowance. No new matter has been added by the requested amendments. It is respectfully urged that the subject application is patentable over references cited by Examiner. Applicant requests reconsideration of the application and allowance of the claims. If there are any outstanding issues that the Examiner feels may be resolved by way of a telephone conference, Examiner is cordially invited to contact David W. Carstens at 972-367-2001.

The Commissioner is hereby authorized to charge any shortages or credit any overpayments to Deposit Account 50-0392.

Respectfully submitted,

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